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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/424,940	03/07/2000	MICHAEL C CRESS	212662-1	8849

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EXAMINER	
NICKOL, GARY B	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/424,940	CRESS ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22 and 24-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22 and 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Re: Cress *et al.*

Date of priority: June 3, 1997

Request for Continued Examination

The request filed on 12-27-2004 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/424940 is acceptable and a RCE has been established. An action on the RCE follows.

Claims 22, and 24-27 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejection Maintained:

In view of the amended claim language, the rejection of Claims 22, 24-26 under 35 U.S.C. 102(b) as being anticipated by Wojtukiewicz *et al.* (Polish Jnl. Pharm., 1996, Vol. 48, pages 229-232) as further evidenced by US Patent No. 4,851,334 (Kudryk *et al.*, 25 July 1989) is reinstated. See Action mailed 07-11-2003, page 3.

To reiterate:

The claims are drawn to a method for detecting cancer in a subject comprising contacting a biological sample obtained from said subject with a monoclonal antibody that binds to a fibrinogen degradation product (FDP) epitope of the beta chain of fibrinogen having an amino acid sequence corresponding to SEQ ID NO:1 and determining the presence or absence of said FDP, wherein fibrin, fibrinogen and fibrinogen fragments D and E are not detected (Claim 22); wherein said monoclonal antibody is generated using an immunogens prepared from a peptide having an amino acid sequence corresponding to SEQ ID NO:2 (Claim 24); wherein said subject is a human mammal (Claims 25-26).

Wojtukiewicz *et al.* teach a method for detecting cancer (gastric cancer) in human subjects comprising contacting a biological sample obtained from said subject with the monoclonal antibody T2G1 (page 230). As evidenced by US Patent No. 4,851,334, the mAB T2G1 is monospecific for a single determinant on the peptide fragment of the beta chain of human fibrin II containing amino acid residues 15-42 (column 5, line 63+). This encompasses a monoclonal antibody generated using an immunogen prepared from a peptide having an amino acid sequence corresponding to SEQ ID NO:2 and which binds to a fibrinogen degradation product (FDP) epitope of the beta chain of fibrinogen having an amino acid sequence corresponding to SEQ ID NO:1 because the specification teaches (page 12, line 18) that SEQ ID NO:2 (or GHRPLDKC) corresponds to amino acids 15-20 of the β-chain of human fibrinogen. Furthermore, US Patent No. 4,851,334 teaches (column 5, line 54) that fibrinogen and fibrin are not detected. And, although, the reference does not specifically teach that fragments D and E are

also not detected, the prior art teaches a method of detecting cancer with the claimed antibody and thus said method would inherently not include the detection of fragments D and E.

Applicants argue (Response, 12-27-2004, pages 4 and 5) that Wojukiewicz *et al.* does not teach a method of detecting cancer, but discloses "experiments investigating the presence of fibrin degradation productions in gastric cancer tissue". Applicants argue that the prior art was interested in thrombosis and DIC in patients with gastric cancer and that nowhere do the authors "suggest that antibodies to fibrin can be used to diagnose cancer by detecting the presence of fibrin degradation products in biological samples". Applicants additionally argue that the prior art's detection of fibrin degradation products in cancer "tissue" is not equivalent to the claimed "biological sample" as defined in the claims.

These arguments have been carefully considered but are not found persuasive. First, the claims are not drawn to a method of *diagnosing* cancer in a subject; rather Claim 1 is broadly drawn to a method of detecting cancer in a subject comprising contacting a biological sample with a monoclonal antibody and determining the presence or absence of a fibrin degradation product. According to Stedman's Medical Dictionary (27th edition), "detection" refers to the mere act of discovery while "diagnosis" relates to the determination of the nature of a disease, injury, or congenital defect. Thus, since the specification does not limit the metes and bounds of what is meant by "detecting", the prior art anticipates the claimed method. Secondly, the specification does not limit the biological sample to those samples mentioned in Claim 27. Claim 27 was not included in the rejection, and thus the prior art's detection of a fibrin degradation product in cancer tissue meets the claimed limitation of a biological sample. Applicants are reminded that claims must be interpreted as broadly as their terms reasonably allow.

In view of the amended claim language, the rejection of Claims 22, and 24-27 under 35 U.S.C. 103(a) as being unpatentable over Wojtukiewicz *et al.* (Polish Jnl. Pharm., 1996, Vol. 48, pages 229-232) and US Patent No. 4,851,334 (Kudryk *et al.*, 25 July 1989) is reinstated; pages 5-6 of Action mailed 07-11-2003.

As set forth previously, Wojutiewicz *et al.* does not specifically teach the presence or absence of a fibrin degradation product in a biological sample selected from the group consisting of blood, serum, plasma, urine, cervical secretions, bronchial aspirates, sputum, saliva, feces, synovial fluid and cerebrospinal fluid (Claim 27).

US Patent No. 4,851,334 successfully teaches methods of detecting fibrinogen degradation products comprising contacting blood or serum with a monoclonal antibody that recognizes an epitope of the beta chain of fibrinogen having an amino acid sequence corresponding to SEQ ID NO:1. The patent further teaches that the assay can be used to measure fibrin degradation products in a number of trauma patient groups including cancer patients (column 14, line 42).

Thus, in combination, the prior art reasonably suggests that fibrin degradation products would successfully be detected in cancer patients using a biological sample selected from the group consisting of blood and serum. Applicant's arguments are similar to those set forth above and are not found persuasive.

New Rejection:

Claims 22, and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 4,851,334 (Kudryk *et al.*, 25 July 1989).

Kudryk *et al.* teaches a method for detecting fibrinogen degradation products (FDP) in a blood sample derived from a human comprising contacting the sample with a monoclonal antibody that binds to a FDP epitope of the beta chain of fibrinogen (column 5, lines 60+). The patent teaches that the mAB T2G1 is monospecific for a single determinant on the peptide fragment of the beta chain of human fibrin II containing amino acid residues 15-42 (column 5, line 63+). Hence, this encompasses a monoclonal antibody generated using an immunogen prepared from a peptide having an amino acid sequence corresponding to SEQ ID NO:2 (see column 9, lines 15+) and which binds to a fibrinogen degradation product (FDP) epitope of the beta chain of fibrinogen having an amino acid sequence corresponding to SEQ ID NO:1 because the specification teaches (page 12, line 18) that SEQ ID NO:2 (or GHRPLDKC) corresponds to amino acids 15-20 of the β-chain of human fibrinogen. The patent further teaches that the assay can be used to measure fibrin degradation products in a number of trauma patient groups including cancer patients (column 14, line 42).

It is noted that applicants have argued (Response, page 5) that the T2G1 monoclonal antibody of Kudryk "may or may not be of equivalent specificity" to the claimed monoclonal antibody of the invention. However, this argument does not constitute objective evidence to the contrary because, in applicant's own words, the T2G1 monoclonal antibody may have the same specificity as the claimed monoclonal antibody.

No claim is allowed.

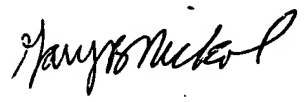
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

GBN



GARY B. NICKOL, PH.D.
PRIMARY EXAMINER